

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

SERGEANTS BENEVOLENT
ASSOCIATION HEALTH & WELFARE
FUND, on behalf of itself and all others
similarly situated,

Plaintiff,

vs.

FOUGERA PHARMACEUTICALS, INC.,
PERRIGO COMPANY PLC, PERRIGO NEW
YORK, INC., SANDOZ, INC., TARO
PHARMACEUTICAL INDUSTRIES, LTD.,
and TARO PHARMACEUTICALS USA, INC.,

Defendants.

Case No. _____

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

Plaintiff Sergeants Benevolent Association Health & Welfare Fund (“SBA Fund” or “Plaintiff”), on behalf of itself and all others similarly situated, brings this Class Action Complaint against Defendants Fougera Pharmaceuticals Inc. (“Fougera”), Perrigo Company PLC (“Perrigo Ireland”), Perrigo New York, Inc. (“Perrigo New York”),¹ Sandoz, Inc. (“Sandoz”), Taro Pharmaceutical Industries, Ltd. (“Taro Israel”), and Taro Pharmaceuticals USA, Inc. (“Taro U.S.A.”),² and alleges as follows:

I. NATURE OF THE ACTION

1. This case centers on an anticompetitive conspiracy among Defendants to raise and fix the prices of the primary formulations of generic Desonide—a widely prescribed topical corticosteroid that health care providers use to treat a variety of skin conditions, such as eczema

¹ Perrigo Ireland and Perrigo New York are collectively referred to as “Perrigo.”

² Taro Israel and Taro U.S.A. are collectively referred to as “Taro.”

and dermatitis. Because Desonide is a lower strength topical drug, physicians often prescribe it for pediatric patients or for adult patients to use in sensitive areas, like the eyelids.

2. Plaintiff brings this civil antitrust action on behalf of a proposed class of end-payors who indirectly purchased, reimbursed, or otherwise paid for (1) generic Desonide topical cream .05%; or (2) generic Desonide topical ointment .05% (collectively, “Desonide”). Plaintiff seeks overcharge damages and other relief arising out of Defendants’ agreement not to compete in the market for generic Desonide.

3. Since June 2013, Defendants Fougera, Perrigo, and Taro have been the primary manufacturers of generic Desonide available for purchase in the United States. Defendant Sandoz acquired Fougera in 2012.

4. Beginning in July 2013, shortly after two meetings of generic pharmaceutical manufacturers attended by Fougera, Perrigo, Sandoz, and Taro, Defendants acted in concert to raise the price of generic Desonide by a dramatic margin. These increases occurred in unison and resulted from Defendants’ horizontal price-fixing agreement.

5. During a single week in July 2013, Defendants collectively raised prices for Desonide more than six-fold, with certain product offerings increasing in price by more than 800%. Whereas, at the beginning of 2013, a 60-gram tube of generic Desonide cream cost \$26.75, as of December 12, 2013, the cost was nearly \$225.

6. Defendants’ prices have stabilized at artificially high levels. As of September 2016, generic Desonide prices remain more than 500% above their pre-July 2013 levels.

7. A report issued in August 2016 by the United States Government Accountability Office (GAO) found that generic Desonide topical cream .05% and generic Desonide topical ointment .05% both “experienced an extraordinary price increase” from 2013 to 2014.

8. Defendants' extraordinary price increases were coordinated. These increases were neither the product of a competitive market, nor made necessary by any increased manufacturing costs. And because generic pharmaceutical manufacturers do not need to incur the research and development costs that brand manufacturers invest to develop new prescription drugs, Defendants' price increases cannot be attributed to the need to fund research and development. Defendants' price increases resulted from their conspiracy to restrain trade.

9. On September 9, 2016, Defendant Taro Israel disclosed that the United States Department of Justice issued subpoenas to Defendant Taro U.S.A. and two of its senior officers as part of the DOJ's ongoing investigation of anticompetitive practices in the generic pharmaceutical industry. The DOJ's subpoenas follow a number of press reports that highlighted concerns about the rising prices of generic Desonide.

10. Defendants' coordinated decision not to compete was designed to and did raise, fix, maintain, or stabilize the price of generic Desonide. As a result, Defendants violated sections 1 and 3 of the Sherman Act, 15 U.S.C. §§ 1, 3, and the various state antitrust and consumer protection laws enumerated below. Plaintiff seeks damages and injunctive relief to prevent Defendants from continuing and maintaining the anticompetitive combination, conspiracy, or agreement alleged in this complaint.

II. JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337 and 15 U.S.C. §§ 1, 3 and 26. This Court has subject matter jurisdiction over the state law claims pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. sections 1332(d) and 1367, in that this is a class action in which there are over 100 members of the Class (as defined herein); the matter in controversy exceeds the sum of

\$5,000,000, exclusive of interest and costs; and at least one member of the Class is a citizen of a state different from that of one of the Defendants.

12. Jurisdiction and venue are proper in this Court under 28 U.S.C. § 1391 because Defendants transact business in this District and Defendants Taro U.S.A. and Perrigo New York maintain their principal places of business in this District. A substantial part of the interstate trade and commerce involved and affected by the violations of the antitrust laws was and is carried on in part within this District. The acts complained of have and will continue to have substantial effects in this District.

III. PARTIES

A. Plaintiff

13. Sergeants Benevolent Association Health & Welfare Fund is located in New York and was established for the purpose of providing benefits to approximately 4,700 active and 7,600 retired New York City Police Department Sergeants and their dependents. As a third-party payor of pharmaceutical claims for its members, the SBA Fund is an indirect purchaser of Desonide and was thereby injured as a result of Defendants' unlawful behavior. The SBA Fund has purchased and/or provided reimbursement for generic Desonide since June 4, 2013, including in California, Florida, Massachusetts, North Carolina, New Jersey, New York, Pennsylvania, Rhode Island, South Carolina, Texas, and Virginia.

B. Defendants

14. Defendant Fougera Pharmaceuticals, Inc. is a New York corporation with its principal place of business in Melville, New York. Fougera markets and sells generic Desonide throughout the United States.

15. Defendant Sandoz, Inc.—a Colorado corporation with a principal place of business in Princeton, New Jersey—is the United States affiliate of Sandoz International GmbH, a company organized and existing under the laws of Germany, having its principal place of business in Holzkirchen, Germany. Sandoz, Inc. is responsible for the distribution of drugs developed and manufactured by Sandoz International. Together, Sandoz International and Sandoz, Inc. operate as the generic pharmaceuticals division of Novartis International AG, a global healthcare company based in Switzerland. In 2012, Novartis acquired Fougere for approximately \$1.5 billion.

16. Defendant Perrigo New York, Inc. is a Delaware corporation with its principal place of business in Bronx, New York. Perrigo New York markets and sells generic Desonide throughout the United States. Perrigo New York is a wholly-owned subsidiary of Defendant Perrigo Company PLC, an Irish company with its principal place of business in Dublin, Ireland.

17. Defendant Taro Pharmaceuticals USA, Inc. is a New York corporation with its principal place of business in Hawthorne, New York. Taro U.S.A. markets and sells generic Desonide throughout the United States. Taro U.S.A. is a wholly-owned subsidiary of Defendant Taro Pharmaceutical Industries Ltd., an Israeli company with its principal place of business in Haifa, Israel.

IV. CO-CONSPIRATORS AND AGENTS

18. The anticompetitive and unlawful acts alleged against the Defendants in this complaint were authorized, ordered, or performed by Defendants and their respective directors, officers, agents, employees, or representatives, while actively engaged in the management, direction, or control of Defendants' business or affairs.

19. Various persons and/or firms not named as Defendants may have participated as co-conspirators in the violations alleged in this complaint and may have performed acts and made statements in furtherance of such violations.

20. Each Defendant acted as the principal, agent or joint venturer of, or for, other Defendants with respect to the acts, violations, and course of conduct alleged in this complaint.

21. The agency relationships formed among the Defendants with respect to the acts, violations, and common course of conduct alleged in this complaint were consensually formed between the Defendant principals and agents. Defendants' agents acted in the United States and abroad within the scope of their agency relationship with their own principals. Defendants' agents acted under the explicit, implied, or apparent authority of their principals. These acts include subsidiaries selling, distributing, or shipping generic Desonide at the request of their parent companies. Further, Defendants acted on behalf of and were subject to the control of their principals, and they acted within the scope of authority or power delegated by their principals. Defendants' agents performed their duties within the scope of their agency, in selling, distributing, or shipping generic Desonide that was sold at supracompetitive prices.

22. Accordingly, the Defendant principals are liable for the acts of their agents. Likewise, the Defendant agents are liable for the acts of their principals conducted by the agents within the scope of their explicit, implied, or apparent authority.

V. INTERSTATE AND INTRASTATE COMMERCE

23. At all material times, Defendants, directly or through one or more of their respective parents, subsidiaries, business units, agents or affiliates, promoted, distributed, sold or delivered substantial amounts of generic Desonide in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

24. At all material times, Defendants transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of generic Desonide.

25. Defendants engaged in conduct both inside and outside of the United States that caused direct, substantial, and reasonably foreseeable and intended anticompetitive effects upon interstate commerce within the United States.

26. Generic Desonide manufactured abroad by the Defendants or their affiliates and sold in the United States constitutes domestic or import commerce.

27. In furtherance of their efforts to restrain competition in the market for generic Desonide, Defendants employed the United States and interstate and international telephone lines, as well as means of interstate and/or international travel. The activities of Defendants were within the flow of and have substantially affected interstate commerce.

28. Defendants' anticompetitive conduct has had substantial intrastate effects in that, among other things, such conduct deprived retailers within each state of access to more affordable generic Desonide that they could sell to end-payors within each state. Defendants' anticompetitive combination, conspiracy, or agreement to reduce competition in the market for generic Desonide has directly affected and disrupted commerce for end-payors within each state.

29. During the relevant time period, generic Desonide was shipped into each state and was sold to or paid for by end-payors. Defendants' conduct as alleged herein has had substantial effects on intrastate commerce in each state because generic Desonide was sold to consumers and third-party payors in each state and Defendants entered into an unlawful, anticompetitive agreement that affected commerce in each state.

VI. FACTUAL ALLEGATIONS

A. Background Regarding Generic Prescription Drugs

30. Bringing a new drug to market is expensive. Accordingly, subject to certain conditions, pharmaceutical manufacturers that invest in research and development and successfully develop and bring to market a new drug are afforded a finite period of exclusivity during which they can market and sell the new drug at higher prices without the threat of competitors offering the same product at lower prices. The exclusivity period is designed to promote a balance between new drug innovation and generic drug competition.

31. Under the Federal Food, Drug, and Cosmetic Act, a manufacturer who creates a new drug product must obtain the approval of the Food and Drug Administration (“FDA”) to sell the new drug by filing a New Drug Application (“NDA”). An NDA must contain specific data concerning safety and effectiveness, among other things.

32. Once the FDA approves a brand manufacturer’s NDA, the brand manufacturer may list the patents identified by the brand manufacturer in “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the “Orange Book.” In the United States it takes an average of over 10 years to bring a new drug to market.

33. The process for bringing a generic drug to market, by contrast, is faster and cheaper. The Hatch-Waxman Act of 1984 simplified the regulatory hurdles for prospective generic manufacturers by simplifying and streamlining the NDA process. A generic manufacturer seeking approval to sell a generic version of a branded drug may instead file an abbreviated new drug application or “ANDA.” An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer’s original NDA, and must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and

strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug. Thus, an ANDA must show that the generic drug is therapeutically equivalent to the branded drug. In addition, as part of the FDA's ANDA approval process, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book.

34. Generic drugs that are therapeutically equivalent to corresponding branded drugs receive an "AB" rating from the FDA, allowing their substitution for the branded drug when an end-payor presents a prescription for the branded drug.

35. Congress enacted the Hatch-Waxman Act to accelerate the market entry of generic competitors to reduce health care expenses across the country. The expedited approval process and exclusivity periods established under Hatch-Waxman were designed to provide consumers with faster, cheaper access to bioequivalent generics while maintaining incentives to innovate in new drug development.

36. Generic drug products fill a critical role in the United States pharmaceutical market because they provide the only form of direct economic and price competition from identical, therapeutically equivalent drug products which can be substituted legally for brand-name drugs. Absent the ability of purchasers to choose an AB-rated therapeutically equivalent generic alternative, branded drugs face little to no competition and can therefore be priced at much higher levels. In short, the presence of AB-rated generic drugs promotes a competitive market for essential prescription drugs.

37. Ordinarily, a generic medication enters the market at a price 10% to 25% below the brand-name price. The price of the generic medication quickly and continually declines as other generic manufacturers enter the product market, until competitive pricing prevails.

B. Consolidation of the Generic Drug Market

38. The global market for generic pharmaceuticals has experienced substantial consolidation since 2005. Generic pharmaceutical industry leader Teva Pharmaceutical Industries Ltd., for example, acquired Ivax Corporation for \$7.4 billion in 2006; Barr Laboratories for \$7.4 billion in 2008; Ratiopharm—Germany’s second largest generic drug producer—for \$5 billion in 2010; and Actavis Generics in 2016 for \$33.4 billion. Other major transactions that occurred during the same time period include Watson Pharmaceuticals’ \$1.9 billion acquisition of Andrx Corporation in 2006; Daiichi Sankyo’s purchase of a majority stake in Ranbaxy in 2008; Endo Pharmaceuticals’ 2010 acquisition of Qualitest for \$1.2 billion; Perrigo’s acquisition of Paddock Laboratories Inc. for \$540 million in 2011; and Sandoz’s acquisition of Fougera for \$1.52 billion in 2012.

39. The generic Desonide market—like the market for most generic drugs—is now highly concentrated. From 2013 to the present, there were only three primary manufacturers of generic Desonide cream and ointment—Defendants Fougera, Perrigo, and Taro.

40. The consequence of the generic drug industry’s consolidation and coordinated pricing activity has been higher prices for consumers. Market consolidation also has resulted in more generic product lines being combined or discontinued, further reducing price competition.

C. Desonide Price Increases

41. Desonide is a low-potency topical corticosteroid that first came to market in the 1970s. Desonide is used to treat swelling, itching, and redness caused by a variety of skin conditions. Because of its relatively low potency, Desonide is widely used to treat skin conditions in children and to treat sensitive areas and folds of the skin in adults.

42. In 2013, Defendants caused the price of generic Desonide to dramatically increase in unison. During a single week in July 2013, the price of generic Desonide increased by a magnitude of several hundred percent. These increases were the subject and product of a horizontal agreement among Defendants to increase pricing and restrain competition.

43. Each of the Defendants met twice in 2013 prior to implementing these price increases. Both meetings occurred at Generic Pharmaceutical Association (GPhA) events.

44. The GPhA describes itself as “the nation’s leading trade association for manufacturers and distributors of generic prescription drugs, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry.” The GPhA was formed in 2000, after the merger of three other generic drug trade associations—the Generic Pharmaceutical Industry Association, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.

45. Defendants Perrigo Ireland and Sandoz sit on the GPhA’s board of directors.

46. Defendants Perrigo Ireland, Sandoz, and Taro Israel attended the GPhA’s Annual Meeting in Orlando, Florida on February 20, 21, and 22, 2013.

47. Defendants Fougera, Perrigo Ireland, Sandoz, and Taro attended the GPhA’s CMC Workshop in North Bethesda, Maryland on June 4 and June 5, 2013.

48. Their meetings in February and June of 2013 provided Defendants with opportunities to collude.

49. Draft National Average Drug Acquisition Cost (“NADAC”) data³ demonstrates that shortly after the CMC Workshop in early June 2013, prices for generic Desonide

³ NADAC is a measure of the cost of drugs developed by the National Association of State Medicaid Directors to set a single national pricing benchmark based on average drug acquisition costs. Draft NADAC price data is precise and accurate, according to the Centers for Medicare and Medicaid Services.

experienced a dramatic, across-the-board increase in price.

50. The NADAC data shows that between July 2013 and January 2014, Defendants increased their prices for generic Desonide in tandem by more than 600%, with certain products increasing by nearly 900%.

51. Defendants have acted in concert to maintain their artificially inflated prices for generic Desonide. As of September 2016, the cost of generic Desonide remains more than 500% higher than the cost prior to the June 2013 trade association meeting.

52. The below tables demonstrate the average Draft NADAC price increases for each Desonide product at issue in this case. Table 1 shows the average price increases carried out by each Defendant at the product level during the week of July 11, 2013. Table 2 shows the average price increases from July 11, 2013 to September 14, 2016, demonstrating that Defendants' pricing of generic Desonide has stabilized at supracompetitive levels.

Table 1
(Percent Increase Per-Unit Between July 11, 2013 and July 18, 2013)

<u>Manufacturer</u>	<u>Amount</u>	<u>.05% Cream</u>	<u>.05% Ointment</u>	<u>Average</u>
Taro	15g	441.74%	389.75%	415.75%
	60g	873.82%	847.69%	860.75%
Perrigo	15g	441.74%	389.75%	415.75%
	60g	873.82%	847.69%	860.75%
Fougera	15g	N/A	389.75%	389.75%
	60g	N/A	847.69%	847.69%
Average		657.78%	618.72%	631.74%

Table 2
(Percent Increase Per-Unit Between July 11, 2013 and September 14, 2016)

<u>Manufacturer</u>	<u>Amount</u>	<u>.05% Cream</u>	<u>.05% Ointment</u>	<u>Average</u>
Taro	15g	288.14%	342.97%	315.56%
	60g	555.98%	747.07%	651.52%
Perrigo	15g	288.14%	342.97%	315.56%
	60g	555.98%	747.07%	651.52%
Fougera	15g	N/A	342.97%	342.97%
	60g	N/A	747.07%	747.07%
Average		422.06%	545.02%	504.03%

53. Defendants' price increases were not necessitated by increased manufacturing costs. They were likewise not incurred to defray research and development costs. Instead, through their anticompetitive agreement to increase and maintain the price of generic Desonide, Defendants were able to substantially increase their revenues without having made investments in research, development, or other costs associated with bringing branded Desonide to market.

D. Factors Corroborating Defendants' Horizontal Price-Fixing Agreement

54. In addition to the pricing data set forth above, several market and other relevant factors give rise to a reasonable inference that Defendants acted unlawfully to raise and fix Desonide prices far above competitive levels. Since at least June 3, 2014, the United States market for generic Desonide has been characterized by numerous factors that facilitated Defendants' conspiracy in restraint of trade, including: (1) market concentration among a limited number of participants; (2) high barriers to entry; (3) mutual interchangeability of Defendants' products; (4) inelasticity of demand; (5) the lack of reasonably available substitutes for the products involved; (6) the absence of a competitive group of sellers; and (7) ease of information sharing among Defendants.

1. Market Concentration

55. Where a market is concentrated among a small number of firms, it is easier for those firms to collude.

56. The market for generic Desonide cream and ointment is highly concentrated. Together, Defendants Fougera, Perrigo, and Taro control nearly all of the market for generic Desonide topical cream .05% and topical ointment .05%.

57. Given the lack of competing manufacturers of generic Desonide, Defendants' concerted actions have had the ability to, and did, affect pricing in the United States.

2. High Barriers to Entry

58. Markets are more susceptible to anticompetitive price manipulation where high barriers to entry exist, such that new, potentially competing firms are dissuaded from entering. Here, high barriers to entry have prevented entry by generic Desonide manufacturers despite the artificial inflation of pricing.

59. Companies seeking to manufacture and sell generic Desonide confront various significant barriers to entry. Manufacturing and intellectual property costs, and regulatory oversight, create substantial hurdles to entry into the generic Desonide market.

3. Mutual Interchangeability of Defendants' Products

60. When products offered by different firms are viewed by purchasers as interchangeable, the suppliers can more easily agree on a single price of the product in question, and effectively monitor pricing to enforce their agreement. Thus, when a product is regarded as a "commodity" that is interchangeable with other products, an anticompetitive cartel can more easily form.

61. Generic drugs are by their nature interchangeable. The generic Desonide products manufactured by Defendants—while formulated differently in certain cases—are each chemical compounds composed of the same raw materials. As such, the generic Desonide products manufactured by Defendants are interchangeable and reasonable substitutes for one another.

4. Inelastic Demand

62. If a given change in price triggers a smaller proportionate change in the quantity demanded, then the demand for the good or service is said to be inelastic. Where demand for a product is inelastic, increases in price cause only limited declines in the quantity of the product sold or consumed in the market.

63. For a cartel to profit from raising prices above competitive levels, demand must be inelastic at competitive prices such that cartel members are able to raise prices without triggering a decline in demand that would make the concerted price increase unprofitable.

64. Generic Desonide is an important and medically necessary drug for millions of people. When untreated, certain of the skin conditions normally treated with generic Desonide can rapidly worsen and result in hospitalization, acute pain and discomfort, and other negative consequences. Therefore, dermatologists and their patients regard Desonide as a medical necessity that must be purchased without regard to an increase in price. Generic Desonide is thus particularly susceptible to collusive price fixing as price increases will directly translate into more revenue for cartel members, rather than less.

5. Lack of Reasonably Available Substitutes

65. While other dermatological drugs on the market seek to treat similar conditions, Desonide—a low-potency topical corticosteroid—is often the only effective medicine that is reasonably available to patients. While other low-potency topical corticosteroids exist, because

Desonide is a well-established and commonly prescribed drug, health care providers face practical difficulties in prescribing suitable alternatives and patients face practical difficulties in accessing equally efficacious alternative medications.

6. Absence of a Competitive Group of Sellers

66. Companies that are not part of the conspiracy can erode cartel members' market shares by offering products at lower, more competitive prices, which in turn erodes cartel revenues. In the market for generic Desonide, there is no realistic threat that a competitive seller or sellers will take market share from Defendants.

67. Defendants maintain oligopolistic power over the market for generic Desonide, which has facilitated their ability to raise, fix, maintain, and stabilize prices without risk of losing market share to firms outside the conspiracy.

7. Ease of Information Sharing Among Defendants

68. As described in paragraphs 43-47 above, Defendants Fougera, Perrigo, Sandoz, and Taro are members of the GPhA. Defendants Perrigo Ireland, Sandoz, and Taro Israel attended the GPhA's Annual Meeting in Orlando, Florida on February 20, 21, and 22, 2013. Defendants Fougera, Perrigo Ireland, Sandoz, and Taro then attended the GPhA's CMC Workshop in North Bethesda, Maryland on June 4 and June 5, 2013 shortly before implementing their Desonide price increases.

69. As part of the DOJ's years-long investigation into anticompetitive pricing activities among generic drug manufacturers, the DOJ is investigating trade associations like GPhA for creating forums for collusion among different generic manufacturers.

70. In this case, Defendants' common membership in GPhA provided them with opportunities to collude by sharing competitive information and collaborating on market strategies with regard to their generic Desonide products.

E. Current United States Antitrust Investigations Into Anticompetitive Practices in the Generic Pharmaceutical Industry

71. Several governmental investigations have been opened in response to the recent drastic price increases in the generic pharmaceutical industry. Multiple congressional investigations were launched, including investigations into Valeant Pharmaceutical International and Turing Pharmaceuticals for their practice of raising prices on older generic drugs. Turing—which increased the price of life-saving drugs—was also the target of antitrust probes by the Federal Trade Commission and the New York attorney general. Mylan NV has come under congressional and regulatory scrutiny for raising the price of the Epipen, with the New York attorney general announcing an investigation of potential antitrust violations based on Mylan's contracts to provide the Epipen to schools. On October 7, 2016, Mylan announced that it had reached an agreement to pay the DOJ and other government agencies \$465 million to settle claims arising from Medicaid-related purchases of the Epipen.

72. According to a December 2015 report prepared by the Office of Inspector General for the United States Department of Health and Human Services, the price of nearly one in four of the top 200 generic drugs rose faster than the price of inflation between 2005 and 2014.

73. In April 2015, the Department of Health and Human Services Inspector General undertook an investigation into the sudden price increases implemented by generic drug manufacturers.

74. In 2014 testimony before the Subcommittee on Primary Health and Aging, pharmaceutical industry experts affirmed (1) the importance of generic drugs to the American

people as an access vehicle to drugs many people otherwise would not be able to afford; and (2) that generic drug prices were not following traditional pricing patterns and were instead experiencing very substantial increases.

75. Over the past year the DOJ has issued subpoenas to a number of generic drug manufacturers including Actavis Plc (now Allergan Plc), Endo International Plc, Lannett Co. Inc., Par Pharmaceutical Holdings Inc., Impax Laboratories Inc., and Mylan N.V. to investigate anticompetitive practices in the generic pharmaceutical industry.

76. On September 9, 2016, Defendant Taro Israel disclosed that on September 8, 2016, Defendant Taro U.S.A. “as well as two senior officers in its commercial team, received grand jury subpoenas from the United States Department of Justice, Antitrust Division, seeking documents relating to corporate and employee records, generic pharmaceutical products and pricing, communications with competitors and others regarding the sale of generic pharmaceutical products, and certain other related matters.”

77. The GAO concluded in August 2016 that generic Desonide .05% topical cream and generic Desonide .05% topical ointment “experienced an extraordinary price increase” between 2013 and 2014.

VII. MARKET DEFINITION

78. Plaintiff need not define a relevant market in connection with its Sherman Act and parallel state law claims because the anticompetitive conduct alleged herein is unlawful per se. The concerted horizontal restraints detailed above elevated the price of generic Desonide cream .05% and generic Desonide ointment .05% far above competitive levels. Defendants’ anticompetitive contract, combination, or conspiracy violates the antitrust laws per se.

79. To the extent a market definition may be relevant to Plaintiff's claims or allegations, the market affected by Defendants' unlawful restraints is the market for generic Desonide cream .05% and generic Desonide ointment .05% in the United States and its territories. Pursuant to their agreement, Defendants eliminated or substantially reduced competition in this market and inflated prices in this market. During the Class period, Defendants were able to profitably maintain the U.S. prices of generic Desonide cream .05% and generic Desonide ointment .05% at supracompetitive levels.

VIII. EFFECTS ON COMPETITION, AND DAMAGES

80. Defendants' combination and conspiracy as set forth in this complaint has had the following effects, among others:

- Competition in the market for generic Desonide has been eliminated or substantially reduced;
- Prices for generic Desonide have increased, and run contrary to the typical pricing patterns of generic drugs;
- United States purchasers have been deprived of the benefit of free and open competition on the basis of price in the market for generic Desonide; and
- As a direct and proximate result of Defendants' illicit anticompetitive conduct, Plaintiff and the Class of end-payors have been injured in their business and property in that, during the Class period, they paid artificially inflated prices for generic Desonide.

81. Plaintiff and the Class have been damaged as measured by the full amount of the overcharges that they paid in an amount subject to proof and to be determined at trial.

82. The foregoing allegations are likely to have evidentiary support after a reasonable opportunity for discovery.

IX. ANTITRUST IMPACT

83. Supracompetitive prices at an upstream level in the chain of distribution ordinarily result in higher prices at every level below. Such is the case here.

84. Wholesalers and retailers passed on the supracompetitive prices of generic Desonide to Plaintiff and Class members, who consequently paid overcharges.

85. Defendants' anticompetitive conduct enabled them to raise, fix, maintain, and stabilize prices to consumers and third-party payors in excess of the prices Defendants otherwise would have been able to charge absent their anticompetitive conduct.

86. The supracompetitive prices paid by Plaintiff and the Class are traceable to, and the direct, proximate, and foreseeable result of, Defendants' illegal concerted pricing policies.

X. CLASS ACTION ALLEGATIONS

87. Plaintiff brings this action on behalf of itself and, under Federal Rules of Civil Procedure 23(a), (b)(1), (b)(2), and (b)(3), as a representative of a Class defined as follows:

All persons or entities

- (1) in the United States, the District of Columbia, and Puerto Rico who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for (a) generic Desonide topical cream .05%; or (b) generic Desonide topical ointment .05% manufactured by Defendants and/or their affiliates in Alabama, Arizona, California, the District of Columbia, Florida, Guam, Hawaii, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Rhode Island, South Dakota, Tennessee, Vermont, West Virginia, and Wisconsin, and/or
- (2) who reside in Alabama, Arizona, California, the District of Columbia, Florida, Guam, Hawaii, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Rhode Island, South Dakota, Tennessee, Vermont, West Virginia, and Wisconsin and indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for (a) generic Desonide topical cream .05%; or (b) generic Desonide topical

ointment .05% manufactured by Defendants and/or their affiliates in the United States, the District of Colombia, or Puerto Rico

for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the “Class”), other than for resale at any time during the period June 4, 2013, through the date the anticompetitive effects of Defendants’ challenged conduct cease (the “Class period”).

88. The following persons or entities are excluded from the Class:

- Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;
- All federal or state governmental entities, excluding cities, towns, or municipalities with self-funded prescription drug plans;
- All persons or entities who purchased generic Desonide for purposes of resale directly from Defendants and their affiliates;
- Fully insured health plans, *i.e.*, plans that purchased insurance from another third-party payor covering 100% of the plan’s reimbursement obligations to its members;
- Any “flat co-pay” consumers whose purchases were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price;
- Pharmacy Benefits Managers; and
- All judges assigned to this case and any members of their immediate families.

89. The Class members are so numerous that joinder is impracticable. Members of the Class are widely dispersed throughout the country. The Class includes at least hundreds of thousands of consumers and at least thousands of third-party payors.

90. Plaintiff’s claims are typical of the claims of all Class members. Plaintiff and all Class members were damaged by the same wrongful conduct by Defendants, *i.e.*, they paid artificially inflated prices for generic Desonide, and were deprived of the benefits of competition as a result of Defendants’ wrongful conduct.

91. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

92. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular expertise with class action antitrust litigation in the pharmaceutical industry.

93. Questions of law and fact common to the Class members predominate over any questions that may affect only individual Class members, because Defendants have acted on grounds generally applicable to the entire Class.

94. Questions of law and fact common to the Class include:

- whether Defendants violated sections 1 and 3 of the Sherman Act, 15 U.S.C. §§ 1 and 3;
- whether Defendants' combination, conspiracy, or agreement constitutes a violation of the state laws set forth below;
- whether Defendants conspired to and did suppress competition in the market for generic Desonide;
- whether Defendants' challenged conduct harmed competition in the generic Desonide market;
- whether, and to what extent, Defendants' conduct as alleged herein caused antitrust injury to the business or property of Plaintiff and Class members in the form of overcharges;
- the quantum of aggregate overcharge damages paid by the class; and
- whether Plaintiff and Class members are entitled to injunctive relief to prevent further violation of sections 1 and 3 of the Sherman Act.

95. Class treatment is a superior method for the fair and efficient adjudication of the controversy, because, among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a similar forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous

individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons and entities with a means of obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in the management of this class action.

96. Class treatment also is appropriate under Rule 23(b)(1) and/or (b)(2) because:

- the prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudications which would establish incompatible standards of conduct for Defendants;
- the prosecution of separate actions by individual Class members would create a risk of adjudication of their rights that, as a practical matter, would be dispositive of the interests of other Class members not parties to such adjudications or would substantially impair or impede other Class members' ability to protect their interests; and
- Defendants have acted and refused to act on grounds that apply generally to the Class such that final injunctive relief and/or declaratory relief is warranted with respect to the Class as a whole.

97. Plaintiff knows of no difficulty to be encountered in the management of this action that would preclude its maintenance as a class action.

XI. CLAIMS FOR RELIEF

CLAIM I

Violations of Section 1 of the Sherman Act, 15 U.S.C. § 1 (Asserted against all Defendants)

98. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

99. This claim is pled as to all Defendants.

100. Beginning at least as early as June 4, 2013, the exact date being unknown to Plaintiff and the Class and exclusively within the knowledge of Defendants, Defendants, acting in concert, entered into a continuing combination or conspiracy to unreasonably restrain trade

and commerce in violation of section 1 of the Sherman Act, 15 U.S.C. § 1, by artificially eliminating or reducing competition in the pricing of generic Desonide in the United States.

101. Defendants combined and conspired to raise, fix, maintain or stabilize the prices of generic Desonide in the United States during the Class period.

102. As a result of Defendants' and their co-conspirators' unlawful conduct and acts taken in furtherance of their horizontal price-fixing conspiracy, prices for generic Desonide sold to purchasers in the United States during the Class period were raised, fixed, maintained or stabilized at artificially inflated levels.

103. The combination or conspiracy among Defendants consisted of a continuing agreement, understanding and concerted action among Defendants and their co-conspirators.

104. For purposes of formulating and effectuating their combination or conspiracy, Defendants and their co-conspirators engaged in anticompetitive activities, the purpose and effect of which were to artificially fix, raise, maintain, and/or stabilize the prices of generic Desonide. Such activities included: (a) participating in meetings to discuss their respective generic Desonide prices and how they could coordinate their market behavior to restrain trade with regard to their generic drug products; (b) agreeing to coordinate and manipulate the prices and available supply of generic Desonide in a manner that deprived United States purchasers of free and open price competition; and (c) providing pretextual justifications to purchasers and the public to explain the changes in the prices for Defendants' generic Desonide.

105. Defendants' concerted anticompetitive acts are illegal per se.

106. As a direct and proximate result of Defendants' illegal anticompetitive conduct, Plaintiff and the Class of end-payors have been injured in their business and property in that they

have paid more for the generic Desonide that they purchased during the Class period than they otherwise would have paid absent Defendants' wrongful conduct.

107. By reason of the foregoing, Plaintiff and the Class are entitled to injunctive relief and a reasonable attorney's fee pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.

CLAIM II
Violations of Section 3 of the Sherman Act, 15 U.S.C. § 3
(Asserted against all Defendants)

108. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

109. This claim is pled as to all Defendants.

110. Beginning at least as early as June 4, 2013, the exact date being unknown to Plaintiff and the Class and exclusively within the knowledge of Defendants, Defendants, acting in concert, entered into a continuing combination or conspiracy to unreasonably restrain trade and commerce in violation of section 3 of the Sherman Act, 15 U.S.C. § 3, by artificially eliminating or reducing competition for the pricing of generic Desonide in any territory of the United States or in the District of Columbia.

111. Defendants combined and conspired to raise, fix, maintain or stabilize the prices of generic Desonide in any territory of the United States or in the District of Columbia during the Class period.

112. As a result of Defendants' and their co-conspirators' unlawful conduct and acts taken in furtherance of their horizontal price-fixing conspiracy, prices for generic Desonide sold to purchasers in any territory of the United States or in the District of Columbia during the Class period were raised, fixed, maintained or stabilized at artificially inflated levels.

113. The combination or conspiracy among Defendants consisted of a continuing agreement, understanding and concerted action among Defendants and their co-conspirators.

114. For purposes of formulating and effectuating their combination or conspiracy, Defendants and their co-conspirators engaged in anticompetitive activities, the purpose and effect of which were to artificially fix, raise, maintain, and/or stabilize the prices of generic Desonide. Such activities included: (a) participating in meetings to discuss their respective generic Desonide prices and how they could coordinate their market behavior to restrain trade with regard to their generic drug products; (b) agreeing to coordinate and manipulate the prices and available supply of generic Desonide in a manner that deprived United States purchasers of free and open price competition; and (c) providing pretextual justifications to purchasers and the public to explain the changes in the prices for Defendants' generic Desonide.

115. Defendants' concerted anticompetitive acts are illegal per se.

116. As a direct and proximate result of Defendants' illegal anticompetitive conduct, Plaintiff and the Class of end-payors have been injured in their business and property in that they have paid more for the generic Desonide that they purchased during the Class period than they otherwise would have paid absent Defendants' wrongful conduct.

117. By reason of the foregoing, Plaintiff and the Class are entitled to injunctive relief and a reasonable attorney's fee pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.

CLAIM III
Conspiracy and Combination in Restraint of Trade in Violation of State Laws
(Asserted against all Defendants)

118. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

119. This claim is pled as to all Defendants.

120. Beginning at least as early as June 4, 2013, the exact date being unknown to Plaintiff and the Class and exclusively within the knowledge of Defendants, Defendants, acting in concert, entered into a continuing combination, conspiracy or agreement to unreasonably restrain trade and commerce in restraint of trade, the purpose and effect of which was to fix, raise, maintain or stabilize the price of generic Desonide.

121. Defendants implemented the terms of their combination, conspiracy, or agreement and achieved their intended purpose. As a direct and proximate result of Defendants' anticompetitive conduct, as alleged herein, Plaintiff and the Class were harmed as set forth above.

122. Defendants' unlawful horizontal combination, conspiracy or agreement harmed competition in the market for generic Desonide.

123. There was and is no legitimate or non-pretextual procompetitive justification for Defendants' coordinated price increases that outweighs their harmful effect. Even if there were some conceivable justification, the coordinated price increases were not necessary to achieve that purpose.

124. By engaging in the foregoing conduct, Defendants entered a conspiracy and combination in restraint of trade in violation of the following state laws:

- Ariz. Rev. Stat. § 44-1402, *et seq.*, with respect to purchases in Arizona by Class members and/or purchases by Arizona residents.
- Cal. Bus. & Prof. Code § 16720, *et seq.*, with respect to purchases in California by Class members and/or purchases by California residents.
- D.C. Code § 28-4501, *et seq.*, with respect to purchases in the District of Columbia by Class members and/or purchases by District of Columbia residents.
- Fla. Stat. § 501.201, *et seq.*, with respect to purchases in Florida by Class members and/or purchases by Florida residents.

- Haw. Rev. Stat. § 480-1, *et seq.*, with respect to purchases in Hawaii by Class members and/or purchases by Hawaii residents.
- Iowa Code § 553.1, *et seq.*, with respect to purchases in Iowa by Class members and/or purchases by Iowa residents.
- Kan. Stat. Ann. § 50-101, *et seq.*, with respect to purchases in Kansas by Class members and/or purchases by Kansas residents.
- Me. Rev. Stat. Ann. 10 § 1101, *et seq.*, with respect to purchases in Maine by Class members and/or purchases by Maine residents.
- Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by Class members and/or purchases by Massachusetts end-payors paying substantially higher prices for generic Desonide in actions and transactions occurring substantially within Massachusetts.
- Mich. Comp. Laws § 445.771, *et seq.*, with respect to purchases in Michigan by Class members and/or purchases by Michigan residents.
- Minn. Stat. § 325D.51, *et seq.*, with respect to purchases in Minnesota by Class members and/or purchases by Minnesota residents.
- Miss. Code § 75-21-1, *et seq.*, with respect to purchases in Mississippi by Class members and/or purchases by Mississippi residents.
- Neb. Rev. Stat. § 59-801, *et seq.*, with respect to purchases in Nebraska by Class members and/or purchases by Nebraska residents.
- Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases in Nevada by Class members and/or purchases by Nevada residents, in that thousands of sales of generic Desonide occurred at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.
- N.H. Rev. Stat. Ann. § 356:2, *et seq.*, with respect to purchases in New Hampshire by Class members and/or purchases by New Hampshire residents.
- N.M. Stat. Ann. § 57-1-1, *et seq.*, with respect to purchases in New Mexico by Class members and/or purchases by New Mexico residents.
- New York General Business Law § 340, *et seq.*, with respect to purchases in New York by Class members and/or purchases by New York residents.
- N.C. Gen. Stat. § 75-1, *et seq.*, with respect to purchases in North Carolina by Class members and/or purchases by North Carolina residents.

- N.D. Cent. Code § 51-08.1-02, *et seq.*, with respect to purchases in North Carolina by Class members and/or purchases by North Dakota residents.
- S.D. Codified Laws Ann. § 37-1-3.1, *et seq.*, with respect to purchases in South Dakota by Class members and/or purchases by South Dakota residents.
- Tenn. Code Ann. § 47-25-101, *et seq.*, with respect to purchases in Tennessee by Class members and/or purchases by Tennessee residents, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for generic Desonide at Tennessee pharmacies.
- W. Va. Code § 47-18-3, *et seq.*, with respect to purchases in West Virginia by Class members and/or purchases by West Virginia residents.
- Wis. Stat. § 133.03, *et seq.*, with respect to purchases of generic Desonide in Wisconsin by Class members and/or purchases by Wisconsin residents, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for generic Desonide at Wisconsin pharmacies.

125. Plaintiff and Class members have been and will continue to be injured in their business or property by reason of Defendants' violations of the laws set forth above, in that Plaintiff and Class members (i) were denied the opportunity to purchase more affordable generic Desonide, and (ii) paid higher prices for generic Desonide than they would have paid but for Defendants' unlawful conduct. Such injuries are of the type that the aforementioned laws were intended to prevent and flow from that which makes Defendants' acts unlawful.

126. Plaintiff and the Class are entitled to actual and trebled damages as permitted by law.

CLAIM IV
Violations of State Consumer Protection Statutes
(Asserted against all Defendants)

127. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

128. This claim is pled as to all Defendants.

129. Beginning at least as early as June 4, 2013, the exact date being unknown to Plaintiff and the Class and exclusively within the knowledge of Defendants, Defendants, acting in concert, engaged in unfair methods of competition, and unfair and unconscionable acts or practices in the course of trade, with respect to the sale of generic Desonide in violation of the following state consumer protection and unfair competition statutes:

- Cal. Bus. & Prof. Code § 17200, *et seq.*;
- D.C. Code Ann. § 28-3901, *et seq.*;
- Fla. Stat. § 501.201, *et seq.*;
- Haw. Rev. Stat. § 480-2, *et seq.*;
- Kan. Stat. Ann. § 50-623, *et seq.*;
- Mass. Gen. Laws chapter 93A § 1, *et seq.*;
- Mich. Comp. Laws § 445.901, *et seq.*;
- Miss. Code § 75-24-1, *et seq.*;
- Neb. Rev. Stat. § 59-1601, *et seq.*;
- N.H. Rev. Stat. Ann. § 358-A:1, *et seq.*;
- N.M. Stat. Ann. § 57-12-1, *et seq.*;
- N.C. Gen. Stat. § 75-1.1, *et seq.*; and
- Rhode Island Gen. Laws § 6-13.1-1, *et seq.*

130. Defendants agreed to, and did, act unfairly in restraint of commerce by affecting, fixing, controlling and/or maintaining, at artificial and supracompetitive levels, the prices at which generic Desonide was sold, distributed, or obtained and made efforts to conceal their agreements from Plaintiff and the Class.

131. Defendants' intentional anticompetitive acts, described above, were intended to and did cause Plaintiff and/or Class members to pay supracompetitive prices for generic Desonide in the states listed above.

132. All of Defendants' unlawful and unfair conduct occurred in the course of their business and was part of a generalized course of conduct.

133. As a direct and proximate result of the Defendants' unfair methods of competition and unfair and unconscionable trade practices, Plaintiff and the Class have been injured in their business and property in that they paid more for generic Desonide than they otherwise would have paid in the absence of Defendants' unlawful and unfair conduct.

134. Plaintiff and the Class are therefore entitled to appropriate relief as provided for by the laws of the states set forth above, including but not limited to damages, injunctive relief, reasonable attorneys' fees, and equitable relief, such as restitution and/or disgorgement of all revenues, earnings, profits, compensation, and benefits Defendants obtained by reason of their unlawful and unfair conduct.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the Class, respectfully requests that the Court:

A. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a), (b)(1), (b)(2), and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the Class, and designate the Plaintiff as the representative of the Class;

B. Enter joint and several judgments against Defendants and in favor of Plaintiff and the Class;

C. Award the Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

D. Grant Plaintiff and the Class equitable relief in the nature of disgorgement, restitution, and establishment of a constructive trust to remedy Defendants' illegal conduct, including:

- i. A judicial determination declaring the rights of Plaintiff and Class members and the corresponding responsibilities of Defendants;
- ii. A declaration that Defendants are to be financially responsible for the costs and expenses of a Court-approved notice program by mail, broadcast media, and publication designed to give immediate notification to Class members;
- iii. Disgorgement and/or the imposition of a constructive trust upon Defendants' ill-gotten gains, thereby freezing Defendants' assets, and/or requiring Defendants to pay restitution to Plaintiff and Class members of all funds acquired by means of any act or practice declared by this Court to violate federal or state statutes or to constitute unfair methods of competition or unfair or unconscionable acts or practices in the course of trade.

E. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided for by law.

XIII. DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff, on behalf of itself and the Class, demands a trial by jury on all issues so triable.

Dated: October 12, 2016

Respectfully Submitted

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